STATE OF RHODE ISLAND

KENT COUNTY, ss. **SUPERIOR COURT**

RONALD MUOIO and BRENDA MUOIO, Plaintiffs, v. LivaNova Holding USA, Inc. and LivaNova USA, Inc., Defendant.	C.A.No. _____

COMPLAINT AND JURY DEMAND

Plaintiffs Ronald Muoio and Brenda Muoio bring this action against Defendants LivaNova Holding USA, Inc. and LivaNova USA, Inc. to recover damages related to and caused by the device known as a Sorin Mitroflow Aortic Heart Value (the "Valve).

PARTIES

1. Plaintiffs Ronald and Brenda Muoio are residents of Kent County, Rhode Island.
2. Defendant LivaNova Holding USA, Inc. – successor in interest to Sorin Group USA, Inc. – is a foreign corporation registered to do business in Rhode Island.
3. Defendant LivaNova USA, Inc. – successor in interest to Cyberonics, Inc. – is a foreign corporation registered to do business in Rhode Island.
4. Defendants share the same principal address and Secretary, and collectively will be referred to herein as Defendants or LivaNova.

JURISDICTION AND VENUE

5. Jurisdiction is proper in this Court because this is a civil matter where the amount in controversy exceeds $10,000.00.

6. Moreover, the Valve regularly made its way into the stream of commerce in Rhode Island, with known sales made by Rhode Island-based sales representatives, living in Rhode Island and selling to local hospitals.

7. Venue is proper because Plaintiffs are residents of Kent County, Rhode Island and Mr. Muoio's treatment arising out of the defective Valve occurred in Rhode Island and also nearby at Massachusetts General Hospital.

FACTUAL BACKGROUND & ALLEGATIONS

PLAINTIFFS' EXPERIENCE WITH THE VALVE

8. Ronald Muoio was a physically fit, sixty-one (61) year old, working full-time, and doing three hundred (300) push-ups daily up until the time he was implanted with the Valve.

9. Mr. Muoio's Valve was implanted in December 2010, at Massachusetts General Hospital.

10. At the time of implant, it was expected by Mr. Muoio, his cardiologist, and his surgeon that the Valve would last at least twenty (20) years.

11. At the time of implant, it was expected by Mr. Muoio and his surgeon that Mr. Muoio would not require further open-heart surgery in his lifetime – at the expected expiration of the Valve, sometime on or around the year 2030, Mr. Muoio would undergo transcatheter aortic valve replacement (TAVR).

12. Things however did not go according to plan.

13. Following implant of the Valve, Mr. Muoio met with his cardiologist for regular follow-up treatment, including echocardiograms.

14. Mr. Muoio inexplicably began to experience a significant loss of energy, shortness of breath, and an overall sense of tiredness.

15. He could no longer complete his daily exercise routine and struggled to perform the labor required by his work and at home.

16. In May 2018, an echocardiogram performed at Kent Hospital in Rhode Island showed prosthetic valve stenosis, requiring immediate replacement of the Valve.

17. In July 2018, Mr. Muoio underwent valve replacement surgery at Massachusetts General Hospital.

18. The surgical procedure to replace the Valve required a second sternotomy that otherwise would not have been required if the Valve had not prematurely failed.

19. Mr. Muoio spent nearly two (2) weeks inpatient after the surgery, spending time in the ICU, dealing with – among other things – fluid in his lungs and a frozen diaphragm.

20. Mr. Muoio continues on a daily basis to suffer pain and must restrict his physical activity as a result of the explant surgery and frozen diaphragm.

21. As a result of Mr. Muoio's unexpected valve replacement surgery, and subsequent loss of his ability to perform physical tasks that were part of his daily routine, Mrs. Muoio was required make additional contributions to the household and suffered loss of consortium damages.

PRODUCT HISTORY

22. The Valve was a Class III medical device manufactured by Sorin Group.

23. LivaNova acquired Sorin Group, its assets and liabilities, and took over the manufacturing, marketing and sales of the Valve.

24. CarboMedics, Inc., also a Sorin Group company and predecessor of LivaNova, applied to the Food and Drug Administration ("FDA") for Pre-Market Approval ("PMA") of the Valve; a process giving it authority to sell the market and sell the Valve with certain protections afforded by the FDCA, including what is widely known as Federal Preemption.

25. A successful PMA means that a manufacturer/distributor of a Class III medical device cannot be the subject of a lawsuit alleging injury from a defective device so long as the information set forth in the PMA application was truthful and the manufacturer/distributor continued to comply with the conditions set forth in the device's PMA approval.

26. PMA for the Valve was issued on October 23, 2007.

27. As part of its PMA application process, applicants are required to provide:

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device

fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 282(j)(5)(B) of title 42 (which shall not be considered an element of such application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

28. The Medical Device Reporting (MDR) regulations contain ongoing mandatory requirements for manufacturers, importers, and device user facilities to report device-related adverse events and product problems to the FDA.

29. With regard to the Valve, LivaNova failed to meet these mandatory requirements by concealing from the FDA the fact that the Valve's bovine membrane had a heightened propensity for early deterioration/calcification in certain patient populations.

30. LivaNova therefore received PMA approval for the Valve by concealing information from the FDA despite having knowledge of particular issues with the Valve's durability and resulting (non)functionality.

31. LivaNova – before and after PMA approval – knew that the Valve had a heightened propensity for valve calcification and deterioration in certain patient populations, including but not limited to those with similar hemodynamics to Mr. Muoio.

32. LivaNova knew or should have known prior to June 19, 2012 that world-wide studies warned the Valve was experiencing rapid premature bovine tissue deterioration and calcification, requiring check-ups more frequent than originally recommended.

33. LivaNova knew or should have known prior to June 19, 2012 that the Valve experienced failure due to rapid premature bovine tissue deterioration and calcification.

34. LivaNova failed to properly update and report to the FDA and end-users LivaNova's knowledge of adverse events concerning the rapid premature bovine tissue deterioration/calcification in Valve recipients.

35. After a 2014 study by Boston Children's Hospital physicians recommended against using the Valve, LivaNova finally addressed the rapid deterioration/calcification problem via a *de facto* recall, removing the Valve from circulation and replacing the Valve with a model containing anti-calcification measures known as Phospholipid Reduction Treatment (hereinafter referred to as "PRT").

36. The PRT technology (or similar anti-calcification/mineralization measures) was widely available and considered industry-standard before Mr. Muoio received his Valve.

37. Had LivaNova provided the FDA and other end-users with accurate information identifying the known risks of rapid bovine tissue deterioration, the Valve would not have been selected for use by Mr. Muoio and his surgeon, and the Valve's failure, leading to a second open-heart surgery and permanent injuries, would not have occurred in Mr. Muoio.

38. LivaNova's efforts to conceal from the FDA and other end-users accurate information concerning the Valve's performance were intentional, malicious and done in bad faith, with the goal of maximizing and prioritizing profits over patient safety.

COUNT I
NEGLIGENCE

39. Plaintiffs repeat and reallege the allegations contained in the paragraphs above as if set forth herein.

40. Plaintiff Ron Muoio hereby makes a common law negligence claim against LivaNova.

41. Plaintiff's negligence claim does not require the imposition of obligations that are different from or in addition to those imposed by the Federal Food Drug and Cosmetic Act (hereinafter referred to as "FDCA").

42. Pursuant to Rhode Island law, LivaNova – as the manufacturer and distributor of the Valve – had a duty to exercise reasonable care and to prevent foreseeable harm to product users.

43. LivaNova's duty under Rhode Island common law is separate and distinct from its Federally mandated reporting requirements pursuant to the FDCA.

44. LivaNova breached its common law duty of care by failing to act as a reasonably prudent manufacturer would have acted under the same or similar circumstances.

45. LivaNova withheld from the FDA and the Valve's end-users adverse event information relevant to the safety and durability of the Valve.

46. Plaintiff, his physicians and health care providers reasonably relied on the information available to them and on the statements of LivaNova that the Valve was fit for use in Mr. Muoio.

47. By reason of LivaNova's negligence, Plaintiff required a second invasive surgery, suffered permanent injury, and sustained significant economic and non-economic damages.

COUNT II
DESIGN DEFECT

48. Plaintiffs repeat and reallege the allegations contained in the paragraphs above as if set forth herein.

49. Plaintiff Ron Muoio hereby makes a common law design defect claim against LivaNova.

50. Plaintiff's design defect claim does not require the imposition of additional obligations that are different from or in addition to those imposed by the FDCA.

51. LivaNova sold in the course of its business the Valve which was implanted in Plaintiff.

52. The Valve was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use.

53. The Valve was used in a manner reasonably anticipated.

54. The Valve's defective condition at the time it was sold directly caused or directly contributed to cause Plaintiff's injuries and resulting damages.

COUNT III
FAILURE TO WARN

55. Plaintiffs repeat and reallege the allegations contained in the paragraphs above as if set forth herein.

56. Plaintiff Ron Muoio hereby makes a common law failure to warn claim against LivaNova.

57. Plaintiff's failure to warn claim does not require the imposition of additional obligations that are different from or in addition to those imposed by the FDCA.

58. LivaNova sold in the course of its business the Valve which was implanted in Plaintiff.

59. The Valve was then unreasonably dangerous when put to a reasonably anticipated use without the knowledge of its characteristics.

60. LivaNova did not give an adequate warning of the danger.

61. The Valve was used in a manner reasonably anticipated.

62. The lack of adequate warning directly caused or directly contributed to cause Plaintiff's injuries and resulting damages.

COUNT IV
LOSS OF CONSORTIUM

63. Plaintiffs repeat and reallege the allegations contained in the paragraphs above as if set forth herein.

64. Plaintiff Brenda Muoio hereby makes a claim for loss of consortium, society and enjoyment of life as a result of the injuries suffered by her husband, Ron.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment against Defendants, and that the Court award Plaintiffs sufficient compensatory and punitive damages for the losses sustained as a result of LivaNova's conduct described herein and to be proven through this litigation.

PLAINTIFFS DEMAND A TRIAL BY JURY.

RONALD MUOIO and BRENDA MUOIO,
By their Attorneys,

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